K130560

KaVo. Dental Excellence.

Section V - 510(k) Summary

Submitter:

Kaltenbach & Voigt GmbH
Bismarckring 39
88400 Biberach
Stefan Trampler - Contact Person
49 (7351) 56 3515 - Phone number
+49 (7351) 56 7 3515 - Facsimile

SEP 27 2013

Date Summary Prepared: August, 28th 2013

Device Name:

- Trade Name - ***MASTERtorque LUX 8900 L***
- Common Name - Dental handpiece and accessories
- Classification Name - Dental handpiece and accessories, per 21 CFR § 872.4200

Devices for Which Substantial Equivalence is Claimed:

- SUPERTORQUE HIGH-SPEED HANDPIECES (K073478)
- HIGH SPEED AIR TURBINE HANDPIECES, PAR-4HEX/4HX SERIES, TWIN Power (K061701)

Device Description:

The *MASTERtorque LUX 8900 L* air-driven handpieces are dental handpieces for the use by a trained professional in the field of general dentistry. The devices are air-powered handpieces that are reusable and ergonomically shaped, and provided with a fiber optic light system. The devices can be sterilized by the steam autoclave method. Through the tube and the MULTIflex coupling connected to a dental unit, the *MASTERtorque LUX 8900 L* receives the air for high speed turbine, the cooling water and air for cutting treatment through pouring holes and light for illumination the operation area. The *MASTERtorque LUX 8900 L* is equipped with the Direct Stop Technology which reduces the stopping time of the high speed turbine and so of the bur. The back suction also will be reduced due to the Direct Stop Technology.

Additionally the *MASTERtorque LUX 8900 L* will be supplied with an exchange filter for the water lines inside of the dental air-driven handpiece. The exchange filter filters the spray water inside the product. The filter is considered to be a spare part. If there is an insufficient amount of cooling water out of the *MASTERtorque LUX 8900 L* according to the instructions for use, this spare has to be exchanged.

Further one there is a jet needle supplied with the *MASTERtorque LUX 8900 L*. By using this part the operator is able to clean the spray holes in the head of the product if there is an insufficient amount of cooling water out of the *MASTERtorque LUX 8900 L* according to the instructions for use.

The KaVo MULTIflex connectors (f.e. MULTIflex coupling 465 LED) are accessories to the medical device which will not be delivered together with the *MASTERtorque LUX 8900 L*. The MULTIflex connectors carry the air for the high speed turbine, the cooling water and air for cutting treatment and light for illumination from the dental treatment unit to the *MASTERtorque LUX 8900 L*.

The mechanism of action for the *MASTERtorque LUX 8900 L* is as follows. The dental handpieces / turbine *MASTERtorque LUX 8900 L* is an air-driven handpiece which will be supplied with water, air and light through the tube and the MULTIflex coupling of a dental treatment unit. Based on the air pressure the turbine rotates up to 400,000 rpms. Dental burs (not part of this 510(k)) according to ISO 1797-1 type 3 could be inserted into the chuck system of the turbine. The *MASTERtorque LUX 8900 L* interacts with the patient through a rotating bur with the patient teeth according to the intended use.

Intended Use of the Device:

The *MASTERtorque LUX 8900 L* is intended for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, removal of fillings, processing and finishing tooth preparations, restorations, and for polishing teeth. They are designed for use by a trained professional in the field of general dentistry.

Substantial Equivalence:

The *MASTERtorque LUX 8900 L* functions in a manner similar to and is intended for the same use as the SUPERTORQUE HIGH-SPEED HANDPIECES marketed by Kaltenbach & Voigt GmbH and to the HIGH SPEED AIR TURBINE HANDPIECES, PAR-4HEX/4HX SERIES, TWIN Power marketed by J. MORITA USA, INC. The *MASTERtorque LUX 8900 L* is similar to the two (2) predicate devices in that it is a dental air-driven handpiece for the use by a trained professional in the field of general dentistry. The *MASTERtorque LUX 8900 L* is substantially equivalent in design, application and function to the two (2) predicate devices noted above. All three devices, the *MASTERtorque LUX 8900 L* and the two (2) predicate devices are reusable and ergonomically shaped. The devices can be sterilized by the steam autoclave method. Based on the run-down behavior the *MASTERtorque LUX 8900 L* is similar to the HIGH SPEED AIR TURBINE HANDPIECES, PAR-4HEX/4HX SERIES, TWIN Power. Both devices are equipped either with the Direct Stop Technology or with the Quick stop. In addition the *MASTERtorque LUX 8900 L* and both predicate devices receives the air for their high speed turbines and the cooling water / air for cutting treatment through the tube and the specific coupling of a dental unit.

The *MASTERtorque LUX 8900 L* differs from the SUPERTORQUE HIGH-SPEED HANDPIECES and the HIGH SPEED AIR TURBINE HANDPIECES, PAR-4HEX/4HX SERIES, TWIN Power in that the *MASTERtorque LUX 8900 L* is only available with a fiber optic light system for illumination of the operation area. Furthermore the *MASTERtorque LUX 8900 L* differs from the SUPERTORQUE HIGH-SPEED HANDPIECES by having the Direct Stop Technology which reduces the stopping time of the high speed turbine and so of the bur. Additionally the back suction will be reduced due to this Direct Stop Technology.

The differences do not render the device NSE because the performance tests demonstrates that the differences in technological characteristics (turbine only with light and the Direct Stop technology) do not raise different questions of safety and effectiveness than the predicate and show that the device is as safe and effective as the predicate.

Summary of the Technological Characteristics:

Descriptive Information	*MASTERtorque LUX 8900 L*	SUPERTORQUE HIGH-SPEED HANDPIECES (K073478)	HIGH SPEED AIR TURBINE HANDPIECES, PAR-4HEX/4HX SERIES, TWIN Power (K061701)
Indications for Use	The *MASTERtorque LUX 8900 L* is intended for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, removal of fillings, processing and finishing tooth preparations, restorations, and for polishing teeth. They are designed for use by a trained professional in the field of general dentistry.	Identical	Identical (The PAR-4HEX/ 4 HX series handpiece is for use by authorized persons in the practice of the dentistry.)
Principle of operation	Through the tube and the MULTIflex coupling connected to a dental unit, the air-powered handpiece receives the air for high speed turbine, the cooling water and air for cutting treatment through pouring holes and light for illumination the operation area.	Identical	Identical
Air / water ports	Up to four (4)	Identical	Three (3)
Fiberoptics	With built-in light system	With and without built-in light system	With and without built-in light system
Dimensions	Headsize-Height: 13,0 mm Headsize-Diameter: 12,5 mm	Headsize-Height: 15,0 mm Headsize-Diameter: 13,0 mm	Headsize-Height: 13,2 mm Headsize-Diameter: 10,5 mm
Type of chuck	Push Button	Identical	Identical
Power (approx.)	23 watts	18 watts	22 watts
Coupling Dimensions	Length with coupling: Approx. 141 mm	Length with coupling: Approx. 130 mm	Length with coupling: Approx. 122,5 mm
Chemical composition of the patient-contacting portions of the device	Stainless steel (See details in Section XV)	German silver and stainless steel	Information not available
Chemical composition of the water / air lines	Stainless steel, german silver (nickel – chromium coated), PEEK and Fluoride Rubber Viton (See details in Section XV)	German silver and stainless steel	Information not available
Light Intensity	Approx. 25,000 LUX	Identical	Identical
Bur retention force	Up to 24 Ncm	Identical	Information not available
Operating Pressure	30 - 61 psi (41 psi recommended)	> 40 psi recommended	19 - 42 psi (35 psi recommended)
Idling Speed	340,000 - 400,000 rpms	Approx. 350,000 rpms	340,000 - 400,000 rpms
Run-down behavior	Direct Stop	Not applicable	Quick Stop

Compliance to Standards	Complies with ISO 7785-1, ISO 7405 and ISO 9168	Identical	Identical
Lubricant	KaVo QUATTROcare (K071288)	Identical	Information not available

Non-Clinical Test Data:

Performance tests according to the international standards for dental air-driven handpieces have been conducted to determine the conformance to the state of the art. Biocompatibility and sterilization studies have been completed which demonstrate that the *MASTERtorque LUX 8900 L* is safe for his intended use.

Clinical Test Data:

Clinical testing has not been conducted on this product.

Conclusion:

Based upon the tests according to the international standards for dental air-driven handpieces, the biocompatibility and sterilization studies and the similar technological / performance characteristics as compared to the predicate devices, the performance of the *MASTERtorque LUX 8900 L* is deemed to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 27, 2013

Kaltenbach & Voight GmbH
Stefan Trampler
Head of Quality Management & Regulatory Affairs
Bismarckring 39
BIBERACH
GERMANY 88400

Re: K130560
Trade/Device Name: MASTERtorque LUX 8900 L
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: August 28, 2013
Received: August 29, 2013

Dear Mr. Trampler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Evaluation
Center for Devices and
Radiological Health

Enclosure

K130560

Section IV - Indications for Use

510(k) Number (if known):

Device Name: ***MASTERtorque LUX 8900 L***

Indications for Use:

The *MASTERtorque LUX 8900 L* is intended for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, removal of fillings, processing and finishing tooth preparations, restorations, and for polishing teeth. They are designed for use by a trained professional in the field of general dentistry.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)

AND / OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
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